

## **II. REMARKS/ARGUMENTS**

Claims 14, 15, 17-20, 22-25, 29, and 31 are pending in the application. Claim 14 has been amended by replacing “or” with --and--.

### **A. Rejection under 35 U.S.C. § 103**

The Examiner has maintained his rejection of claims 14-20 and 22-25 under 35 U.S.C. § 103 as allegedly being obvious over U.S. Patent No. 4,826,680, by Jaeger. Applicant traverses for the reasons explained below.

The Examiner alleges that Jaeger teaches pharmaceutical compositions that contain riboflavin and the amino acids glycine, alanine, serine, threonine, valine, and arginine. The Examiner alleges that the Jaeger compositions contain the very same components as those instantly claimed. The Examiner states that the only distinction between the Jaeger composition and the instant invention is that the instant claims use the transitional language “consisting of,” whereas Jaeger uses “comprising.” The Examiner argues that Jaeger specifically teaches and provides motivation to use riboflavin in the presence of arginine, and alanine, glycine, serine, threonine, and valine to make pharmaceutical preparations.

The Jaeger compositions contain a mixture of two organ extracts. The first extract contains low molecular proteins and/or oligo-peptides and the second extract contains riboflavin associated with organ specific oligo-peptides. The Examiner alleges that it is irrelevant that the Jaeger composition is directed to proteins/oligo-peptides and the instant claims are directed to free form amino acids because the Examiner believes that the proteins/oligo-peptides will naturally metabolize into individual amino acids in the body. The Examiner alleges that the

instantly claimed amino acid compositions would be obvious in view of the protein/oligo-peptide compositions of Jaeger. The Examiner's reasoning is faulty for two reasons:

1) One of skill in the art would appreciate that the proteins/oligo-peptides of Jaeger would lose their biological activity if they were hydrolyzed into their component amino acids.

Jaeger is directed to compositions to simulate the immune system and treat immune deficiency diseases. *See*, Jaeger abstract. Jaeger recognizes that the thymus gland regulates the immunologic system of the body and that such functions can be performed by protein extracts from the thymus gland. *See*, col. 1, ll. 7-10. Jaeger is directed to two thymus extracts consisting of low molecular weight proteins and/or oligo peptides. *See*, col. 1, ll. 64-68.

One of skill in the art would recognize that the three-dimensional structure of proteins and/or oligo peptides is largely responsible for their specific biological activity. One of skill in the art would not expect a composition of free amino acids to possess the same biological activity as the active protein. This is one reason that certain precautions must be taken when isolating proteins for biological studies, i.e., care must be used to insure that the proteins do not decompose to the constituent amino acids. *See, for example*, Jaeger, col. 3, ll. 14-20 (describing the use of filtered, sterilized or distilled water and inert atmosphere and sterile conditions for filtration) and col. 3, ll. 27-43 (describing the use of stabilizers and lyophilization).

It is true that Jaeger describes hydrolyzing the proteins and/or oligo peptides to the constituent amino acids, but this is for the purpose of chemical identification. Jaeger does not teach or suggest the pharmaceutical use of amino acids in the free form and one of skill in the art would not expect free form amino acids to possess the same biological activity as the intact, undenatured proteins and/or oligo peptides. Hydrolyzing the proteins/oligo-peptides of Jaeger to

their free form amino acids would render the Jaeger compositions ineffective for their intended purpose.

The instant claims are not directed to pharmaceutical compositions for immunostimulation and immunoregulation and they do not depend on pharmacologically active proteins. Rather, the instant claims are directed to compositions useful for alleviating or reducing fatigue and weakness associated with cancer and cancer chemotherapy by providing the patient with riboflavin and specific amino acids. The specific amino acids are chosen because they provide nutritional support but do not promote cancer growth. This is fundamentally different than the compositions of Jaeger, which comprise pharmacologically active proteins and/or oligo peptides.

2) Even if the proteins and/or oligo peptides of Jaeger hydrolyzed to their substituent amino acids, the resulting composition would not be within the instant claims because the Jaeger proteins/oligo peptides include amino acids that are excluded by the instant claims. The proteins/oligo peptides of Jaeger break down into the 18 amino acids listed in Table I at col. 11. Only 6 of the 18 amino acids listed in Table I are included in the instant claims. The closed “consisting of” language of the instant claims excludes the other amino acids from the claimed compositions. Furthermore, the instant claims recite taurine, which is not taught or suggested in the Jaeger reference.

The Examiner stated that the closed “consisting of” language does not prevent Jaeger from rendering the instant claims obvious because Jaeger teaches “the very same pharmaceutical components.” Jaeger does not teach “the very same pharmaceutical components.” Jaeger teaches proteins/oligo-peptides; the instant claims are directed to free form amino acids. The proteins/oligo-peptides of Jaeger include about 12 amino acids that are excluded by the

“consisting of” language of the instant claims. Even if the Jaeger proteins/oligo-peptides hydrolyzed to their constituent amino acids, the resulting composition would include amino acids that are excluded by the instant claims. Jaeger does not provide any motivation to exclude two-thirds of the amino acids contained in the proteins/oligo-peptides taught therein. The Examiner has not pointed to any other reference that suggests to use free form amino acids or to exclude two-thirds of the amino acids that make up the Jaeger proteins/oligo-peptides. Moreover, the Examiner has not provided any reference that suggests including taurine with the compositions taught by Jaeger. Jaeger does not come close to teaching the “very same pharmaceutical components” as the instant claims.

Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 103.

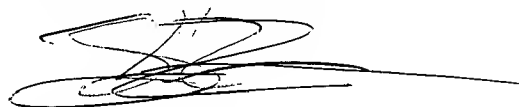
**B. Allowable Subject Matter**

The Examiner has indicated that claims 29 and 31 are allowed. Applicant respectfully thanks the Examiner for indicating allowable subject matter and submits that the remaining claims are also allowable, in light of the arguments presented above. Applicant respectfully requests that the Examiner issue an Advisory Opinion if he does not find the present arguments persuasive.

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The Examiner is invited to contact the undersigned patent agent with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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